

**Comments on texts resulting from the Terrestrial Animal Health Code Commission
Report – January 2005 Meeting
Submitted by the United States of America**

PROPOSED THREE CATEGORY VERSION

BOVINE SPONGIFORM ENCEPHALOPATHY

General Comments

The United States commends the work the OIE has done to continue to update and refine the Code Chapter on Bovine Spongiform Encephalopathy, particularly as it strives to do so using technical information that is well grounded and which has withstood rigorous scrutiny by the scientific community.

Having reviewed the latest proposed draft Chapter, the United States supports the OIE's proposed recommendations made to Article 1, Item 1) which lists commodities that can be traded regardless of the BSE status of a country. Specifically, the United States supports the changes which specify that *all* hides and skins of bovine origin can be traded regardless of the BSE status of a country, zone or compartment. Hides and skins and gelatin prepared exclusively from such hides and skins are safe and should not require any BSE related restrictions regardless of the BSE status of the cattle population in the exporting country.

The United States also supports the OIE's recommendations to add de-boned skeletal muscle (excluding mechanically separated muscle) and blood and blood products to the list of products that can be traded regardless of the BSE status of a country. Carefully conducted clinical studies have failed to show that bovine skeletal muscle tissue is a risk for harboring the BSE agent. Similarly, BSE infectivity has never been detected in blood or other blood components. Despite intensive research trials and detailed epidemiological evidence, BSE infectivity has not been detected in bovine blood in either natural or experimental cases.

References:

Bradley, R. 1999. BSE transmission studies with particular reference to blood. *Dev. Biol. Stan.* 99:35-40.

Fraser, H., Bruce, M., Chree, A., McConnel, I., and Wells, G. 1992. Transmission of BSE and scrapie to mice. *J. of General Virology.* 73:1891-1897.

Moon, Harley W. 1996. BSE: Hypothetical risk of emergence as a zoonotic food-borne epidemic. *J. of Food Protection.* 59: 1106-1111

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Finally, and under this section of “General Comments”, the United States would like the OIE’s Code Commission to consider adding the following language at the beginning of the BSE Code Chapter:

“Countries should not prohibit products that are of non-bovine origin because of BSE”

Rationale: Many importing countries have used BSE as an excuse to prohibit the trade in non-bovine origin animal products against exporting countries that report BSE.

Specific comments

Article 1

The recommendations in this Chapter are intended to manage the human and animal health risks associated with the presence of the bovine spongiform encephalopathy (BSE) agent in cattle (*Bos taurus* and *B. indicus*) only.

- 1) When authorising import or transit of the following *commodities* ~~and any or products made from these commodities that do not contain and containing no other tissues from cattle~~, *Veterinary Administrations* should not require any BSE related conditions, regardless of the BSE risk status of the cattle population of the exporting country, ~~zone~~ or *compartment*.

Rationale: the suggested edited changes help clarify the statement.

Article 2

1)

...

b) Exposure assessment

~~If the release assessment identifies a risk factor, an~~ An exposure assessment should be conducted, consisting of assessing the likelihood of exposure of the BSE agent to cattle, through a consideration of the following:

Rationale: Procedurally, according to OIE, there are three elements of risk assessment. The elements are: Release assessment (R), Exposure assessment (E), and Consequence assessment (C). Risk=R*E*C. The three elements must be completed for each import request, given the difficulty in establishing a zero-risk justification. The release assessment will be product-, source-, and pathway-dependant. All three elements must be developed with anticipation of connectivity with each other.

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Article 9

When importing from a country, *zone* or *compartment* posing a negligible BSE risk without commodity-specific risk mitigation measures ~~mitigating measures~~, *Veterinary Administrations* should require:

for fresh meat and meat products from cattle (other than that listed in point 1) of Article 1)

the presentation of an *international veterinary certificate* attesting that:

...

- 2) ~~ante-mortem and post-mortem inspections were carried out on all cattle from which the fresh meat or meat products originate. the cattle from which the fresh meat and meat products were derived were subjected to and passed ante-mortem and post-mortem inspections.~~

Rationale: The suggested changes lend better clarity to the statement

Article 10

When importing from a country, *zone* or *compartment* posing a negligible BSE risk with commodity-specific risk mitigation measures ~~mitigating measures~~, *Veterinary Administrations* should require:

for fresh meat and meat products from cattle (other than those listed in point 1) of Article 1)

the presentation of an *international veterinary certificate* attesting that:

- 1) the country, *zone* or *compartment* complies with the conditions in Article 4;
- 2) ~~ante-mortem and post-mortem inspections were carried out on all cattle from which the fresh meat or meat products originate. the cattle from which the fresh meat and meat products were derived were subjected to and passed ante-mortem and post-mortem inspections.~~
- 3) cattle from which the *fresh meat* and *meat products* destined for export originate were not subjected to a stunning process, prior to slaughter, with a device injecting compressed air or gas into the cranial cavity, or to a pithing process (laceration, after stunning, of central nervous tissue by means of an elongated rod-shaped instrument introduced into the cranial cavity);
- 4) the *fresh meat* and *meat products* ~~do not contain~~ were processed in a manner which ensures that such products do not contain and are not contaminated with:

....

Rationale: The suggested changes make the intent of this article clearer.

Article 11

When importing from a country, *zone* or *compartment* with an undetermined BSE risk, *Veterinary Administrations* should require:

for fresh meat and meat products from cattle (other than those listed in point 1) of Article 1)

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the presentation of an *international veterinary certificate* attesting that:

...

- 2) the *fresh* meat and *meat products* ~~are derived from deboned meat and~~ do not contain:
- a) the tissues listed in Article 13,
 - b) nervous (trigeminal ganglia, dorsal root ganglia, and spinal cord) and lymphatic tissues (tonsil and distal ileum) exposed during the deboning process,
 - c) mechanically separated meat from the skull and vertebral column,
- all of which have been completely removed in a manner to avoid contamination of the *fresh meat* and *meat products* ~~these tissues~~.

Rationale: The text under Item 2) b) is added for clarity. All fresh meat and meat products contain various amounts of nervous and lymphatic tissue, and thus, may not be completely removed during the de-boning and cutting processes. We believe that the intent of this section of the Code is that fresh meat and meat products do not contain the nervous and lymphatic tissues described in our suggested text.

Article 13

- 1) ...
- 2) From cattle that were at the time of slaughter over 30 months of age originating from a country, ~~zone~~ or ~~compartment~~ defined in Articles 4 and 5, the following commodities, and any commodity contaminated by them, should not be traded for the preparation of food, feed, fertilisers, cosmetics, pharmaceuticals including biologicals, or medical devices: brains, eyes, spinal cord, skull, trigeminal ganglia, dorsal root ganglia, vertebral column and derived protein products. Food, feed, fertilisers, cosmetics, pharmaceuticals or medical devices prepared using these commodities should also not be traded.

Rationale: Suggest adding these tissues to the list of SRMs because they have demonstrated infectivity.

Article 14

Veterinary Administrations of importing countries should require:

for gelatin and collagen prepared from bones ~~or from hides and skins from the head~~ and intended for food or feed, cosmetics, pharmaceuticals including biologicals, or medical devices

the presentation of an *international veterinary certificate* attesting that the *commodities* came from:

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- 1) a country, ~~zone~~ or ~~compartment~~ posing a negligible BSE risk without commodity-specific risk mitigation ~~mitigating~~ measures; or
- 2) a country, ~~zone~~ or ~~compartment~~ posing a negligible BSE risk with commodity-specific risk mitigation ~~mitigating~~ measures; and
 - a) skulls and vertebrae (except tail vertebrae, ~~and hides and skins from the head~~), and if from cattle over 30 months of age have been excluded;
 - b) the bones have been subjected to a process which includes all the following steps:
 - i) pressure washing (degreasing),
 - ii) acid demineralisation and/or
 - iii) prolonged alkaline treatment,
 - iv) filtration,
 - v) sterilisation at $\geq 138^{\circ}\text{C}$ for a minimum of 4 seconds,or to an equivalent process in terms of infectivity reduction.

Rationale:

- 1) Adding the age-specification criteria under 2) a) aligns Article 14 with Articles 13 and 15.
- 2) Studies have shown that gelatin is safe for human and animal consumption whether such gelatin is processed by acid de-mineralization or by prolonged alkaline treatment.